

The Examiner has rejected claims 1, 2 and 7-10 under 35 U.S.C. 102(b) as being anticipated by Jobe (US 5,787,713) as teaching a staple made of shape memory material and comprising a cross bar 74 and two outwardly directed legs 72, Fig. 16. Posts 14, 72 in the staple of Jobe have been designed for providing increased resistance to oppose forces substantially parallel to the bone surface and retain the bone sections in place. Either the inwardly and outwardly directed legs are designed to provide retention of the staple into the bone to retain tissue against bone or bone against bone. However, there is neither disclosure nor suggestion of the use and design of the staple of Jobe for controlling the epiphyseal plate and for accommodating the growth of the bone in order to prevent the staple from being expelled by the bone during growth. The mere reference to "encourage distraction" in column 10, line 7 of Jobe is not enough to show that Jobe had designed his staple for use in a bone for controlling growing, with the outwardly directed legs being capable of accommodating the growth of the bone. All references to the behavior and function of the staple made by Jobe indicate that the aim of the staple is just to enhance retention into the bone tissue. The staple of the invention is therefore quite different from the one of Jobe.

Additionally, there is nothing described by Jobe in connection to the main function of the cross bar other than the purpose thereof to retain a tissue against the bone. The cross bar of the present invention, however, has been constructed and designed to arrest and control the growth plate while the legs are constructed for exerting an expansion force into the bone far from the periphery thereof, as recited, for example, in independent claim 1.

Thus, it is clear that the construction, function, purpose and aim of the staple of the present invention is very different from the description in the Jobe patent.

The foregoing discussion is also important with respect to the §103(a) rejection of claim 3, which recites that the shape memory material is NITINOL. Since Jobe has designed the staple to retain tissue against bone it is quite probable that most of the staple installations are made through deep and wide incisions in the patient's body and therefore an enormous tool 41 can be used outside the body to bend the staple in order to place their legs parallel, see Fig. 14, and to pass through the incision. Such a large tool, however, can only be used if a wide incision is made to accede to the broken bones or the tendon that must be fixed to the bone, as explained in the specification of Jobe.

Different from the above, the staple of the present invention accedes to the epiphyseal plate of a bone that is not broken. Accordingly, no deep or wide incision is necessary as long as the bone is healthy and only a malformation is to be corrected without the need of opening the tissues traumatically. This operation may be made by an endoscopy technique by introducing an inductor through which a staple made of Nitinol is delivered into the body and installed in the bone. This is made possible because the staple is made of Nitinol, which is a material that keeps its normal shape at the body temperature, while at low temperatures, such as 0°C, the material is entirely malleable. As explained in the present specification, the staple is frosted (frozen) to bring the same to the appropriate configuration for installation and, once installed in the bone, the staple returns to its original shape.

In addition to the foregoing, there is another important feature of the present inventive staple that is distinct not only as to structure, but also as to operation is concerned. The staple of Jobe is claimed and disclosed as having the cross bar deformable between the leg portions to move the leg portions from an initial orientation to an insertion orientation. This is necessary because Jobe employs tool 41 that grips bar 74 to bend the same. Bar 74 is pre-deformed to facilitate this bending and, when the fixation apparatus has been inserted in the bone, bar 74 remains in the bend position extending out of the bone surface. It is noted, for instance, that if the staple of Fig. 16 of Jobe is compressed to place the legs parallel, cross bar 74 bends upwardly. This is the shape it will retain as long as the stress in the legs is not released.

Different from Jobe, the staple of the present invention does not rely on a tool. Instead the staple is integrally deformed and, if the cross bar would be upwardly deformed, since the bone is growing at the side of the epiphyseal plate, after a period of time the legs return to their original divergent position without any stress remaining in the staple body. Any remaining stress causes the staple to be expelled out from the bone. Significantly, the staple of the present invention has been designed to control the growing of a bone by arresting the undesired growing (at the bone's periphery) and facilitating the desired development of the malformed bone (at a distance from the bone's periphery). This is clearly different from the device of Jobe.

Regarding claims 14 and 15, which have been rejected as being anticipated by Oberlander (U.S. 6,554,852), Applicant respectfully disagrees with the position taken in the Office Action. Oberlander does not disclose a staple, but a suture to retain tissue against tissue. While the staple recited in claim 14 should be removed from the bone once a desired growing

has occurred, Oberlander does not need to remove the anchor suture and, if the suture is not absorbable and must be removed, anchors 21 may be removed by unscrewing the same out from the bone. This unscrewing is possible thanks to the provision of rotating collars 45 that permit removal of anchors 21 without the need of cutting the suture. The suture of Oberlander has not been designed to be cut and removed after the healing period, therefore the claimed invention, namely, a cross bar to be cut combined with threaded (23-25) legs is different from the device disclosed by Oberlander.

In view of the foregoing all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone applicants' undersigned representative at the number listed below.

SHAW PITTMAN LLP  
1650 Tysons Boulevard  
McLean, VA 22102  
Tel: 703/770-7900

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Respectfully submitted,

JORGE ABEL GROISO

By:

  
Michael D. Bednarek  
Registration No. 32,329